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FISCAL IMPACT STATEMENT

LS 6119

BILL NUMBER: HB 1020

NOTE PREPARED: Jan 15, 2008

BILL AMENDED:

SUBJECT: Umbilical Cord Blood Bank.

FIRST AUTHOR: Rep. Welch

FIRST SPONSOR:

BILL STATUS: As Introduced

FUNDS AFFECTED: X GENERAL
DEDICATED
X FEDERAL

IMPACT: State

Summary of Legislation: The bill requires the Office of the Secretary of Family and Social Services to enter into a memorandum of understanding with a nonprofit corporation to establish and operate an umbilical cord blood bank. The bill establishes the nonprofit corporation.

The bill requires physicians and participating hospitals to inform pregnant patients of the option to donate umbilical cord blood. It also requires the nonprofit corporation to establish an umbilical cord blood donation initiative to promote public awareness concerning the medical benefits of umbilical cord blood.

(The introduced version of this bill was prepared by the Health Finance Commission.)

Effective Date: July 1, 2008.

Explanation of State Expenditures: *Summary-* The cost of the public umbilical cord blood bank will depend on the General Assembly to appropriate funds, the amount of private donations available to subsidize the public cord blood bank, the amount of revenue to be realized from sales, and subsequent administrative actions taken by the Office of the Secretary of the Family and Social Services Administration (FSSA) to negotiate an agreement to administer the program. Approximately \$1.06 M is estimated to be required for direct collection, testing and banking costs necessary for the public umbilical cord blood bank to reach the minimum size required to apply for federal grant funds. This estimate does not include administrative, marketing, or training costs required by the bill that would depend on administrative actions. The availability of federal grant funds is on a competitive basis.

Background and Additional Details-

As a point of reference, the National Marrow Donor Program has estimated that 5 to 7 years and approximately \$10 M to \$16 M is necessary to develop and annually store sufficient units in a cord blood bank for the bank to reach a break-even point on an annual cash flow basis. Additionally, the Texas Cord Blood Bank established in 2004 has received state appropriations of \$6.2 M and was awarded \$1.66 M in federal funds in the 2007 round of HRSA competitive grants.

The bill establishes a nonprofit corporation that FSSA is required to contract with to establish and provide for the operation of a public umbilical cord blood bank. The Board of Directors is to consist of nine members: the Commissioner of Health, the Secretary of FSSA, the Secretary of Commerce, the Director of the Office of Minority Health and five individuals with specific professional credentials to be appointed by the Governor. The Board is required to appoint an advisory board to be responsible for reviewing applications for the purchase of cord blood or placentas determined to be ineligible for transplant use. The bill also authorizes the Board to contract for the management and administrative operations of the public umbilical cord blood bank. The cost of this provision would depend on appropriations, other financial resources that would be available, and administrative actions of the Board.

The bill requires the nonprofit corporation to educate health care professionals about the procedures necessary to collect and maintain umbilical cord blood donations following the birth of an infant. The corporation is required to develop forms concerning patient informed consent and privacy. The corporation is required to establish a public awareness initiative to promote (1) the importance of donating to a public cord blood bank and (2) the opportunity to donate umbilical cord blood on the birth of an infant. The public awareness campaign must include the distribution of written materials containing specified information to specified persons and licensed facilities.

The bill requires each physician and participating hospital to inform each pregnant patient within 30 days after the beginning of the patient's third trimester of the opportunity to donate umbilical cord blood to the public bank. The bill specifies that a patient may not be charged for the collection, storage, or donation to the public umbilical cord blood bank.

Startup Funding Estimate: The U.S. Department of Health and Human Services, Health Resources and Services Administration, requires that public cord blood banks have 600 transplantable cord blood units and a viable minority outreach program developed before an application will be accepted for competitive grants currently available to expand the national cord blood inventory. In order to reach the level necessary to apply for federal funding (600 units) it is estimated that only 30% of the total collected units will ultimately be placed in the bank due to stringent quality standards that must be met. This would require the initial collection of at least 2,000 cord blood units. Testing costs are significant, with the direct cost of testing reported to be between \$1,000 and \$1,700 for each unit banked. Testing costs for collected units that are discarded prior to storage are estimated to be approximately \$500 per unit. Annual storage costs for banked units are estimated to average \$50 per unit. Total testing cost required to reach the number of banked units necessary to apply for federal funding is estimated to range from \$1,315,000 to \$1,735,000.

Collection costs are assumed to be donated by the participating hospitals. If collection costs cannot be absorbed by the hospitals, this could result in additional expense to the public cord blood bank. Collection of the cord blood units includes the completion an extensive medical history by the mother as well as the collection of the cord blood. As a point of reference, Medicaid currently has a \$55 charge for medically necessary aspiration of cord blood. If only collection costs for the aspiration of cord blood at the Medicaid

reimbursement would be paid by the public cord blood bank, an additional \$110,000 would be necessary for the collection of the first 2,000 units.

Existing cord blood banks are reported to experience a transplant utilization rate of less than 1% with the charge for a transplantable unit being approximately \$15,000. If this experience is assumed to apply to the first 600 banked cord blood units, 6 matches might be expected. \$90,000 may be realized in revenue from this source.

The bill also allows the cord blood bank to make units not eligible for banking available for research purposes. Umbilical cord blood units or placentas used for research purposes may be sold for \$185 to \$505 depending on the level of processing performed. This source of revenue is estimated to generate revenue in the range of \$259,000 to \$707,000.

It is assumed that the collection program will be subject to a phased implementation with the initial program being implemented in the Indianapolis metropolitan area to include Marion and the surrounding counties. This geographic area had 25,600 live births in 2005, about 30% of the total annual births in the state. If only 10% agree to donate their child's cord blood (2,600), the program would have more than the volume estimated to be necessary to bank the initial 600 units required to apply for federal funding. (The associated costs would also be higher as well.)

The bill requires the nonprofit corporation to establish an umbilical cord blood donation initiative to promote public awareness of the purposes of cord blood banking and the opportunity to donate to a public cord blood bank. This information is required to be distributed in a written format. The program is also required to educate health care professionals about collection procedures and requirements as well as other administrative requirements to implement the cord blood bank. The cost of these provisions will depend on the number of initial participating hospitals and physicians.

Other State Initiatives: The New York Blood Center, one of the largest public cord blood banks with about 35,000 cord blood units, reports that processing a unit of cord blood costs between \$1,000 and \$2,000 depending on how it is collected and stored and the location of the bank. This bank reported that their operations "about break-even" since they have such a large inventory of units. Most of the nearly two dozen public banks in the country rely on private donations to operate.

Federal initiatives are making limited funding available with the intent of increasing the national inventory of cord blood units available. The U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), awarded \$12 M in grants in 2006 to the first group of cord blood banks to begin collections for the National Cord Blood Inventory. A second round of competitive grants was distributed to the original six grantees plus two additional cord blood banks in September 2007. HRSA requires that public cord blood banks have 600 transplantable cord blood units and have a viable minority outreach program developed before an application will be accepted for the competitive grants.

Several states have funded the startup and operations of state-sponsored cord blood banks. New York announced construction of a new \$10 M umbilical cord blood bank to be operated by the State Health Department's Wadsworth Laboratory with about 20 employees.

Texas started the Texas Cord Blood Bank in 2004 with a \$1 M startup grant, promising up to \$3.5 M in matching funds for the facility. The first unit of cord blood was collected in June 2005; in November of the same year, the facility was awarded another \$1.2 M in state matching funds after reaching 1,000 collected

units. The facility has also been raising funds in the community. In May 2007, the Texas legislature appropriated another \$4 M to assist in the collection of cord blood units. Additionally, the Texas Cord Blood Bank was awarded \$1.66 M in federal funds in the 2007 round of HRSA competitive grants. As of November 2007, the Texas Cord Blood Bank reported six participating hospitals in the state. Texas officials reported that the program needed to collect about 6,000 units to be financially self-sustaining.

New Jersey appropriated \$2.5 M annually in April 1998. However, in 2006 the appropriation and the authorizing language was discontinued.

Explanation of State Revenues:

Explanation of Local Expenditures: Participating county-owned hospitals would be required to offer each maternity patient the option of donating the cord blood following delivery at the facility.

Explanation of Local Revenues:

State Agencies Affected: Family and Social Services Administration, Office of Medicaid Policy and Planning.

Local Agencies Affected:

Information Sources: *Report to the General Assembly, Public Act 06-77, An Act Concerning the Establishment of a Public Umbilical Cord Blood Bank*, January 5, 2007, J. Robert Gavin, MD, MPH, Commissioner, Department of Public Health, State of Connecticut at [Cord Blood, Establishing a National Hematopoietic Stem Cell Bank Program](http://www.ct.gov/dph/lib/dph/governmental_relations/2007reports/public_umbilical_cord_blood_bank_report.pdf), Committee on Establishing a National Cord Blood Stem Cell Bank http://www.ct.gov/dph/lib/dph/governmental_relations/2007reports/public_umbilical_cord_blood_bank_report.pdf. Program, Institute of Medicine of the National Academies, at: http://www.nap.edu/openbook.php?record_id=11269&page=221.

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